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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,304

11/02/2006

Hidekazu Tonouchi

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EXAMINER

NIEBAUER, RONALD T

ART UNIT

PAPER NUMBER

1654

NOTIFICATION DATE

DELIVERY MODE

04/01/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SUGHRUE265550@SUGHRUE.COM  
USPTO@SUGHRUE.COM  
PPROCESSING@SUGHRUE.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,304	<b>Applicant(s)</b> TONOUCHI ET AL.	
	<b>Examiner</b> RONALD T. NIEBAUER	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
- 4a) Of the above claim(s) 17-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/4/10</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicants amendments and arguments filed 1/15/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn. Briefly, the 112 and 101 rejections have been overcome by applicants amendments.

Previously, applicants elected without traverse of Group I (claims 11-16) and the following peptide: MAP (i.e. SEQ ID NO:1) in the reply filed on 5/29/09.

It is noted that applicants have deleted SEQ ID NO:1 from claim 11. Further, claim 11c recites that when n is 0, m is not 0. Thus the elected peptide does not read on claim 11. In the instant case, previously cited art reads on claim 11. As such, in accord with section 803.02 of the MPEP the claims have been searched to the extent necessary to determine patentability.

Claims 17-18 and newly added claims 24-25 are drawn to a non-elected group. Newly added claims 19-23 are drawn to non-elected species (as stated above applicants previously elected MAP for which art was found - see previous office action).

Claims 17-18,24-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/29/09.

Claims 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/29/09.

Claims 1-10 have been cancelled.

Claims 11-16 are under consideration.

***Claim Rejections - 35 USC § 102***

The previous 102 rejections based on Cohen (US 2002/0172692) and Parry et al (WO 02/098448) are withdrawn based on the claim amendments. Claims were previously rejected under 102 based on Reid. Since the claims have been amended the rejection is updated to correspond to the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 11-16** are rejected under 35 U.S.C. 102(b) as being anticipated by Reid et al (Appl Microbiol Biotechnol “comparison of bovine b-casein hydrolysis by P1 and Piii-type proteinases from Lactobacillus lactis subsp. cremoris” (1991) 36:344-351) .

Reid et al (Appl Microbiol Biotechnol (1991) 36:344-351) teach that bovine beta-casein hydrolysis was compared by using various proteinases (abstract). In figure 4, Reid teach the peptide sequence of bovine beta-casein (page 348). Reid teach that amino acids 102-104 are Met-Ala-Pro (page 348). Thus the naturally occurring bovine beta-casein comprises Met-Ala-Pro (i.e. SEQ ID NO:1 of the instant invention) as recited in the instant claims. In relation to claim 11c the peptide of Reid is such that n and m are 1. Further, Reid teach that specific digested portions of the beta-casein were isolated (see Table 1) and in figure 7a (page 349) state

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that residues 193-209 of the casein are in peak 11. Reid teach that HPLC peak 11 contains the peptide comprising Met-Ala-Pro (Table 1). As such, the peptide was necessarily in a composition as recited in claims 14,16. It is noted that claim 12 recites that the peptide is an inhibitor for an angiotensin-converting enzyme. Since Reid teach the peptide such peptide would have the claimed property (see MPEP section 2112.01). It is noted that claim 13 recites the words 'food or drink'. Since Reid teach that HPLC peak 11 contains the peptide comprising Met-Ala-Pro (Table 1) such composition is in a form suitable for food or drink. It is noted that claims 15-16 recite that the agent is for treating diseases. Such statement regarding the use is an intended use as it does not limit the composition to a particular structure. Thus Reid teach the limitations of claims 11-16 of the instant invention.

***Response to Arguments 102 rejection***

Since the claims have been amended an updated rejection adapted to the claims is recited above using the same reference as in the previous rejection. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue (pages 8-9) that the cited references do not disclose the amino acids as set forth in claim 11.

Applicant's arguments filed 1/15/10 have been fully considered but they are not persuasive.

Although Applicants argue (pages 8-9) that the cited references do not disclose the amino acids as set forth in claim 11, it is noted that claim 11 is drawn to peptides of particular sequences. Section 2111.03 of the MPEP states that consisting of is closed language. However,

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such language does not appear in claim 11. Further, the instant specification (page 18 Table 2, page 3 lines 18-19) sets forth peptides comprising Met-Ala-Pro. As such, it is consistent with the specification and section 2111 of the MPEP to read claim 11 as open. Even though claim 11c refers to n and m, such variables do not suggest closed language. Since claim 11c recites that when n is 0, m is not 0 the peptide must comprise at least 4 amino acids. However, the claims do not exclude peptides longer than 4 amino acids.

### ***Conclusion***

Claims were previously rejected under 102. Since the claims have been amended the rejection above has been updated to correspond to the instant claims. Thus, applicants amendments have necessitated any new grounds of rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/  
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/  
Examiner, Art Unit 1654